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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,077	01/04/2002	Terry J. Amiss	P-5430	9417

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EXAMINER	
ALEXANDER, LYLE	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	10/040,077	AMISS ET AL.
	Examiner	Art Unit
	Lyle A Alexander	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *17-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claim Rejections - 35 USC § 112

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants are claiming trademarked labels. Applicant must claim the compound and not the trademarked compound because the composition of the trademarked product may change. Additionally, Applicants claims "Dapoxyl ® " which is not clear and should be deleted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 and 1-12 of copending Application No. 10/039,833 and 10/039,799 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a biosensor using the same mutated binding protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kratzch et al.

Kratzch et al. teach in paragraph [0008] glucose biosensors using s-GDH(glucose dehydrogenase) are well known in the art. In paragraphs [0002] + teach the instant invention is to creating an improved s-GDH variant by mutating the binding proteins.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hellinga(6,277,627), Hellinga (6,521,446) or Lakowicz et al.

These references all teach use of a mutated protein in combination with a glucose biosensor.

Claims 1-5 and 11-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Marvin et al. (J AM. Chem. Soc. 1998,120,7-1 cite by Applicants), Marvin et al. (Proc. Natl. Acad. Sci. cited by Applicant) or Tolosa (Analytical Biochemistry 267, 114-120(1999) cited by Applicants).

These references all teach glucose biosensors using a mutated binding protein to quantify glucose using fluorescent measurements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marvin et al. (J AM. Chem. Soc. 1998,120,7-1 cite by Applicants), Marvin et al. (Proc. Natl. Acad. Sci. cited by Applicant) or Tolosa (Analytical Biochemistry 267, 114-120(1999) cited by Applicants).

These references all teach glucose biosensors using a mutated binding protein to quantify glucose using fluorescent measurements. These references are all silent to the claimed positions of amino acid substitution.

The court decided In re Boesch (205 USPQ 215) the optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known results. The art all modify amino acids at different positions than claimed. The choice of which amino acids to modify is a result effective variable and within the skill of the art.

It would have been within the skill of the art to modify Marvin et al. (J AM. Chem. Soc. 1998,120,7-1 cite by Applicants), Marvin et al. (Proc. Natl. Acad. Sci. cited by

Applicant) or Tolosa (Analytical Biochemistry 267, 114-120(1999) cited by Applicants) and modify the amino acids at the claimed positions as optimization of a result effective variable.

Claims 6-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellinga(6,277,627), Hellinga (6,521,446) or Lakowicz et al.

See Hellinga(6,277,627), Hellinga (6,521,446) and Lakowicz et al. supra.

These references are all silent to the claimed positions of amino acid substitution and the claimed luminescent labels.

The court decided In re Boesch (205 USPQ 215) the optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known results. The art all modify amino acids at different positions than claimed. The choice of which amino acids to modify is a result effective variable and within the skill of the art. Additionally, the choice of label to achieve its well-known and expected function as a label is also a result effective variable.

It would have been within the skill of the art to modify Hellinga(6,277,627), Hellinga (6,521,446) or Lakowicz et al. and modify the claimed amino acids at the claimed positions as optimization of a result effective variable.

The claimed luminescent labels are well known in the art as evidenced the trademarks and copyright notations associated with the labels. For example Quantum Red ™, Texas Red ™, etc. The compounds are well known in the art to perform the function of a fluorescent label and are commercially available. It is desirable to use

commercially available labels because they are readily available and accessible to others so the work can be readily duplicated.

It would have been within the skill of the art to further modify Hellinga(6,277,627), Hellinga (6,521,446) or Lakowicz et al. and use well known fluorescent labels, such as Quantum Red ™, Texas Red ™, etc., to gain the above advantages and as optimization of a result effective variable.

Claims 17-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

Lyle A Alexander
Primary Examiner
Art Unit 1743

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